

Introduced by Senator Correa

January 21, 2014

An act to amend Section 1256.01 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 906, as introduced, Correa. Elective Percutaneous Coronary Intervention (PCI) Pilot Program.

Existing law establishes, until January 1, 2015, the Elective Percutaneous Coronary Intervention Pilot Program in the State Department of Public Health, which authorizes up to 6 eligible acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria, to perform scheduled, elective primary percutaneous coronary intervention (PCI), as defined, for eligible patients. Existing law establishes an advisory oversight committee to oversee, monitor, and make recommendations to the department concerning the pilot program. Existing law also imposes various reporting requirements on the advisory oversight committee and the department, including recommendations as to whether the pilot program should be continued or terminated and whether elective PCI without onsite cardiac surgery should be continued in California.

This bill would make technical, nonsubstantive changes to those provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1256.01 of the Health and Safety Code is amended to read:

1256.01. (a) The Elective Percutaneous Coronary Intervention (PCI) Pilot Program is hereby established in the department. The purpose of the pilot program is to allow the department to authorize up to six general acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet the requirements of this section, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

(b) For purposes of this section, the following terms have the following meanings:

(1) “Elective Percutaneous Coronary Intervention (elective PCI)” means scheduled percutaneous transluminal coronary angioplasty and stent placement. Elective PCI does not include urgent or emergent PCI that is scheduled on an ad hoc basis.

(2) “Eligible hospital” means a general acute care hospital that has a licensed cardiac catheterization laboratory and is in compliance with all applicable state and federal licensing laws and regulations.

(3) “Interventionalist” means a licensed cardiologist who meets the requirements for performing elective PCI at a pilot hospital.

(4) “Pilot hospital” means a hospital participating in the Elective Percutaneous Coronary Intervention (PCI) Pilot Program established by this section.

(5) “Primary percutaneous coronary intervention (primary PCI)” means percutaneous transluminal coronary angioplasty and stent placement that is emergent in nature for acute myocardial infarction and that is performed before administration of thrombolytic agents.

(6) “Receiving hospital” means a licensed general acute care hospital with cardiac surgery services that has entered into a transfer agreement with a pilot hospital.

(7) “STEMI” means ST segment elevation myocardial infarction, a type of heart attack, or myocardial infarction, that is caused by a prolonged period of blocked blood supply, which affects a large area of the heart muscle, and causes changes on an electrocardiogram and in the blood levels of key chemical markers.

1 (8) “Transfer agreement” means an agreement between the
2 eligible hospital and the receiving hospital that meets all of the
3 requirements of this section.

4 (c) To participate in the pilot program, an eligible hospital shall
5 demonstrate that it complies with the recommendations of the
6 Society for Cardiovascular Angiography and Interventions (SCAI)
7 for performance of PCI without onsite cardiac surgery, as those
8 recommendations may evolve over time, and meets all of the
9 following criteria:

10 (1) Performs at least 36 primary PCI procedures annually, has
11 the capacity to perform at least 200 primary and elective PCI
12 procedures annually, and by year two of participation in the pilot
13 program, actually performs at least 200 primary and elective
14 procedures, including at least 36 primary PCI procedures.

15 (2) Has an on-call schedule with operation of the cardiac
16 catheterization laboratory 24 hours per day, 365 days per year.

17 (3) Performs primary PCI as the treatment of first choice for
18 STEMI, and has policies and procedures that require the tracking
19 of door-to-balloon times, with a goal of 90 minutes or less, and
20 requires that outlier cases be carefully reviewed for process
21 improvement opportunities.

22 (4) Permits only interventionists who meet the following
23 requirements to perform elective PCI under the pilot program:

24 (A) Perform at least 100 total PCI procedures per year, including
25 at least 18 primary PCI per year.

26 (B) Have lifetime experience of at least 500 total PCI procedures
27 as primary operator.

28 (C) Have complication rates and outcomes equivalent or superior
29 to national benchmarks established by the American College of
30 Cardiology.

31 (D) Hold board certification by the American Board of Internal
32 Medicine in Interventional Cardiology and Cardiovascular
33 Diseases.

34 (E) Actively participate in the eligible hospital’s quality
35 improvement program.

36 (5) Employs experienced nursing and technical laboratory staff
37 with training in interventional laboratories. Cardiac catheterization
38 laboratory personnel shall have demonstrated competency treating
39 acutely ill patients with hemodynamic and electrical instability.

(6) Employs experienced intensive care unit nursing staff who have demonstrated competency with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Nursing personnel shall be capable of managing endotracheal intubation and ventilator management both onsite and during transfer, if necessary. The eligible hospital shall demonstrate sufficient staffing capacity in the intensive care unit to provide posttreatment care for patients undergoing elective PCI.

(7) Has a well-equipped and maintained cardiac catheterization laboratory with high resolution digital imaging capability and intraaortic balloon pump support compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data via T-1 transmission line as well as audio and video images to review terminals for consultation at the receiving hospital is ideal.

(8) Has an appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, and pericardiocentesis trays. Pressure wire devices and intravascular ultrasound equipment are optimal, but not mandatory.

(9) Provides evidence showing the full support from hospital administration in fulfilling the necessary institutional requirements, including, but not limited to, appropriate support services such as respiratory care and blood banking.

(10) Has a written transfer agreement for the emergency transfer of patients to a facility with cardiac surgery services. Transport protocols shall be developed and tested a minimum of twice per year, and shall ensure the immediate and efficient transfer of patients, within 60 minutes, 24 hours per day, seven days per week, from the eligible hospital to the receiving hospital. The time for transfer of patients shall be calculated from the time it is determined that transfer of a patient for emergency cardiac surgery is necessary at the eligible hospital, to the time that the patient arrives at the receiving hospital.

(11) Has onsite rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.

(12) Participates in the American College of Cardiology-National Cardiovascular Data Registry.

(13) Provides evidence in its application that demonstrates the use of rigorous case selection for patients undergoing elective PCI. Patient selection criteria will meet all of the following requirements, or otherwise be consistent with the recommendations of the SCAI, as those recommendations may evolve.

(A) Patient selection shall be based on the interventionalist's professional medical judgment, which may include, but is not limited to, consideration of the patient's risk, the patient's lesion risk, and the patient's overall health status.

(B) For purposes of this section, "patient risk" means the expected clinical risk in case of occlusion or other serious complication caused by the procedure. "High patient risk" may include, but is not limited to, patients with any of the following features: ~~decompensated~~

(i) *Decompensated* congestive heart failure (Killip class III) without evidence for active ischemia, recent cardiovascular attack, advanced malignancy, or known clotting ~~disorders~~; ~~left disorders~~.

(ii) Left ventricular ejection fraction less than or equal to 25 percent; ~~left percent~~.

(iii) Left main stenosis greater than or equal to 50 percent or three-vessel disease unprotected by prior bypass surgery greater than 70 percent stenosis in the proximal segment of all major epicardial coronary ~~arteries~~; ~~or a arteries~~.

(iv) A single target lesion that jeopardizes over 50 percent of remaining viable myocardium.

(C) For purposes of this section, "lesion risk" means the probability that the procedure will cause acute vessel occlusion or other serious complication. "High lesion risk" may include, but is not limited to, lesions in open vessels with any of the following characteristics: ~~diffuse~~

(i) *Diffuse* disease (greater than two centimeters in length) and excessive tortuosity of proximal ~~segments~~; ~~more segments~~.

(ii) *More* than moderate calcification of a stenosis or proximal ~~segments~~; ~~location segments~~.

(iii) *Location* in an extremely angulated segment (greater than 90 ~~percent~~); ~~inability percent~~).

(iv) *Inability* to protect major side ~~branches~~; ~~degenerated branches~~.

(v) *Degenerated* older vein grafts with friable ~~lesions~~; ~~substantial lesions~~.

1 (vi) *Substantial* thrombus in the vessel or at the lesion site; and
2 any site.

3 (vii) Any other feature that may, in the interventionalist's
4 judgment, impede stent deployment.

5 (D) In evaluating patient risk and lesion risk to determine patient
6 eligibility for inclusion in the pilot program, the interventionalist
7 shall apply the strategy set forth by the SCAI as set forth below,
8 or as it may otherwise evolve:

9 (i) A high-risk patient with a high-risk lesion shall not be
10 included in the pilot program.

11 (ii) A high-risk patient with a not high-risk lesion may be
12 included in the pilot program upon confirmation that a cardiac
13 surgeon and an operating room are immediately available if
14 necessary.

15 (iii) A not high-risk patient with a high-risk lesion may be
16 included in the pilot program.

17 (iv) A not high-risk patient with a not high-risk lesion may be
18 included in the pilot program.

19 (14) Will include evidence of institutional review board (IRB)
20 approval of its participation in the pilot program for as long as
21 ACC/AHA/SCAI guidelines categorize elective PCI with offsite
22 cardiac surgery as a Class III indication.

23 (15) Shall demonstrate evidence of the process for obtaining
24 written informed consent from patients prior to undergoing elective
25 PCI. The application shall include a copy of the eligible hospital's
26 informed consent form applicable to elective PCI. Evidence of
27 IRB approval of the informed consent form will also be provided
28 for as long as ACC/AHA/SCAI guidelines categorize elective PCI
29 with offsite cardiac surgery a Class III indication.

30 (d) Consistent with this section, the department shall invite
31 eligible hospitals to submit an application to participate in the
32 Elective PCI Pilot Program. The applications shall include
33 sufficient information to demonstrate compliance with the
34 standards set forth in this section, and additionally include the
35 effective date for initiating elective PCI service, the general service
36 area, a description of the population to be served, a description of
37 the services to be provided, a description of backup emergency
38 services, the availability of comprehensive care, and the
39 qualifications of the general acute care hospital providing the
40 emergency treatment. The department may require that additional

1 information be submitted with the application. Failure to include
2 any required criteria or additional information shall disqualify the
3 applicant from the application process and from consideration for
4 participation in the pilot program. The department may select up
5 to six general acute care hospitals for participation in the Elective
6 PCI Pilot Program based on the applicant's ability to meet or
7 exceed the criteria described in this section.

8 (e) An advisory oversight committee comprised of one
9 interventionalist from each pilot hospital, an equal number of
10 cardiologists from nonpilot hospitals, and a representative of the
11 department shall be created to oversee, monitor, and make
12 recommendations to the department concerning the pilot program.
13 In designating the cardiologists from nonpilot hospitals to the
14 committee, the department shall consider the recommendations of
15 the California Chapter of the American College of Cardiology.
16 The advisory oversight committee shall submit at least two reports
17 to the department during the pilot period. The oversight committee
18 shall conduct a final report by November 30, 2013, including
19 recommendations for the continuation or termination of the pilot
20 program.

21 (f) If at any time a pilot hospital fails to meet the criteria set
22 forth in this section for being a pilot hospital or fails to safeguard
23 patient safety, as determined by the department, that pilot hospital
24 shall be removed from participation in the pilot program by the
25 department.

26 (g) Each pilot hospital shall provide quarterly reports to the
27 department and the oversight committee that include statistical
28 data and patient information relating to the number of elective PCI
29 procedures performed, the interventionalists performing elective
30 PCI procedures, and the outcomes of those procedures. In addition,
31 pilot hospitals shall include in the report recommendations, if any,
32 for modifications to the pilot program and any other information
33 the pilot hospitals deem relevant for evaluating the success of the
34 pilot program in delivering improved patient care. The department
35 and the oversight committee may make site visits to any pilot
36 hospital at any time.

37 (h) Notwithstanding Section 10231.5 of the Government Code,
38 within 90 days of receiving the final report of the oversight
39 committee, the department shall prepare and submit a report to the
40 Legislature, pursuant to Section 9795 of the Government Code,

1 on the initial results of the Elective PCI Pilot Program. The report
2 shall include, but not be limited to, an evaluation of the pilot
3 program's cost, safety, and quality of care. The report shall also
4 include a comparison of elective PCI performed in connection
5 with the Elective PCI Pilot Program, and elective PCI performed
6 in hospitals with onsite cardiac surgery services. The report shall
7 further recommend whether elective PCI without onsite cardiac
8 surgery should be continued in California, and if so, under what
9 conditions.

10 (i) The department may charge pilot hospitals a supplemental
11 licensing fee, the amount of which shall not exceed the cost to the
12 department of overseeing the pilot program.

13 (j) The department may contract with a professional entity with
14 medical program knowledge to meet the requirements of this
15 section.

16 (k) This section shall remain in effect only until January 1, 2015,
17 and as of that date is repealed, unless a later enacted statute, that
18 is enacted before January 1, 2015, deletes or extends that date.